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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,881	11/02/1999	MICHELINE MARKEY	15662-000900	1727

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/432,881

Applicant(s)

MARKEY ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-26, 32-34, 47-55 and 97-151 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14-26, 32-34 47-55, and 97-151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1</u> _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims:

The response filed **May 11, 2006** presents remarks and arguments to the office action mailed **January 05, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Claims 1-9, 14-26, 32-34 47-55 and 97-151 are pending in this application.

Claims 1-9, 14-26, 32-34 47-55 and 97-151 have been amended.

Claims 1-9, 14-26, 32-34 47-55 and 97-151 are been examined.

Claims 1-9 and 14-18 are rejected.

Claim Rejections - 35 USC § 112

Claims 1-9, 14-26, 32-34 47-55, and 97-151 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "solid matrix" is not define by the claim and the specification does not provide a standard for ascertaining the requisite degree, one of skill in the art would not be reasonably apprised of the scope of the invention.

Response to Arguments

Applicants' arguments, filed May 11 to the office action have been fully considered but they are not deemed to be persuasive. The following rejections and/or

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objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1 and 14-18 remain rejected under 35 U.S.C. 102(b) as being anticipated by MacKenzie et al., Fundamental and Applied toxicology.

Applicants' argument that the MacKenzie reference calls for toxicity feeding studying, and that the instant claims are for administration of fed mode inducing agents as part of a composition.

In response, this is found unpersuasive.

MacKenzie et al., teach the reduction of body weight/mass in individuals receiving the instant active agents (alkali and alkaline earth metal docusates) in claims 1 and 14-18. (See abstract). As to the solid matrix, the specification does not indicate whether the drug is the solid matrix or the drug is comprised of a solid matrix. The above cited references contain all the limitation of the rejected claims. See page 53 the references teaches clearly that the (dioctyl sulfocinate (DSS) is used in a variety of pharmaceutical and food additive contrary to Applicants traverse.

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II. Claims 49-55 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/47285 ('285) is withdrawn argument persuasive.

III. Claims 1 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kais et al., US Patent 5,516,524 ('524).

Applicant argues that the above claim rejection takes place in the colon and not in the stomach.

In response, Applicant is arguing a limitation that is not set forth in the claim clearly. The medication is taken orally, fed, thus goes to the stomach and not the colon.

The above rejection is maintained. It meets the claim limitations it inherently anticipates the use. Relieving constipation induces at least a degree of fed mode within the scope of the instant claims. Since, '524 meets all elements of the instant claims, this method also inherently anticipates the intended use of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Claims 1-9 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/47285 ('285) taken with MacKenzie et al., Fundamental and Applied toxicology.

Applicants' traverse that there is no basis in the cited art for combining these references.

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, combining the above cited reference would have motivated one of ordinary skill in the art because the teachings of McKenzie is the DSS in food or drugs. As stated last there is no definition that states that the solid matrix cannot be the drug and no such definition for a solid matrix. Applicant's arguments have been fully considered but they are not persuasive. And the above rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
7/13/06


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER